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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,324	06/29/2006	Gisela Greif	Le A 36 695	3066
35969	7590	11/02/2007	EXAMINER	
JEFFREY M. GREENMAN			LEE, JAE W	
BAYER PHARMACEUTICALS CORPORATION			ART UNIT	
400 MORGAN LANE			PAPER NUMBER	
WEST HAVEN, CT 06516			1656	
			MAIL DATE	DELIVERY MODE
			11/02/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/562,324

Applicant(s)

GREIF ET AL.

Examiner

Jae W. Lee, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Application status***

Claims 1-19 are pending in the instant application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-5, 12 and 13, drawn to a polynucleotide comprising: a) the sequence as depicted in SEQ ID NO: 1 or 3; or b) a polynucleotide which exhibits an identity of more than 50% with the polynucleotide having the sequence depicted in SEQ ID NO: 1 or 3; or c) a polynucleotide, which hybridizes under stringent conditions, with the polynucleotide having the sequence as depicted in SEQ ID NO: 1 or 3; or d) a polynucleotide which encodes a polypeptide having the sequence depicted in SEQ ID NO: 2; or e) a polynucleotide which exhibits an identity of more than 50% with a polynucleotide which encodes the polypeptide having the sequence depicted in SEQ ID NO: 2; or f) a polynucleotide which hybridizes under stringent conditions with a polynucleotide which encodes the polypeptide having the sequence depicted in SEQ ID NO: 2; or g) a polynucleotide which differs from a polynucleotide having the sequence depicted in SEQ ID NO: 1 due to the degeneracy of the genetic code; h) a polynucleotide which is a fragment of a polynucleotide as described in a) to g) and is at least 6 nucleotides in length; and a vaccine.

Group II, claim(s) 2, 12 and 13, drawn to a polypeptide which is encoded by a polynucleotide as claimed in claim 1 and is at least 8 amino acids in length; and a vaccine.

Group III, claim(s) 6, 7 and 10-13, drawn to an antibody, characterized in that it specifically binds to the polypeptide as claimed in claim 2; and methods of its use.

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Group IV, claim(s) 8 and 9, drawn to a method for detecting a polynucleotide as claimed in claim 1, wherein a polynucleotide as claimed in claim 1 is hybridized with the nucleic acid material from a biological sample and the hybridization is detected.

Group V, claim(s) 14 and 15, drawn to a method for finding active compounds which modulate the activity of the EtOS22 protein during the excystation of sporozoites from sporocysts, in which: a) the active compound to be tested is brought into contact with an EtOS22 polypeptide as claimed in claim 2, with the selected conditions enabling the test substance to bind specifically to the EtOS22 polypeptide; and b) a specific binding to the polypeptide which has taken place is detected; with an active compound which binds to the polypeptide being identified as a potential active compound for treating coccidiosis.

Group VI, claim(s) 16-19, drawn to an active compound which can be found using one of the methods as claimed in claim 14 or 15.

In addition to the above election, please elect a single SEQ ID NO. This application contains claims directed to the following patentably distinct species: SEQ ID NO: 1, SEQ ID NO: 3.

The species are independent or distinct because these SEQ ID NOs represent structurally different polynucleotide/polypeptide sequences. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

These claims will be examined to the extent they read upon the elected species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-19 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The reference of Andrews et al. (US Patent No. 5,187,080) teaches the cDNA sequences isolated from the genomic DNA of *Eimeria Tenella*, which anticipates claim 1, in the recitation of "a polynucleotide comprising: b) a polynucleotide which

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exhibits an identity of more than 50% with the polynucleotide having the sequence depicted in SEQ ID NO: 1 or 3; or c) a polynucleotide, which hybridizes under stringent conditions, with the polynucleotide having the sequence as depicted in SEQ ID NO: 1 or 3; or d) a polynucleotide which encodes a polypeptide having the sequence depicted in SEQ ID NO: 2; or e) a polynucleotide which exhibits an identity of more than 50% with a polynucleotide which encodes the polypeptide having the sequence depicted in SEQ ID NO:2; or f) a polynucleotide which hybridizes under stringent conditions with a polynucleotide which encodes the polypeptide having the sequence depicted in SEQ ID NO:2; or g) a polynucleotide which differs from a polynucleotide having the sequence depicted in SEQ ID NO: 1 due to the degeneracy of the genetic code; h) a polynucleotide which is a fragment of a polynucleotide as described in a) to g) and is at least 6 nucleotides in length," and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are unrelated and distinct for the reasons given above, and the literature and sequence searches required for each of the Group is not required for another thereby presenting a search burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

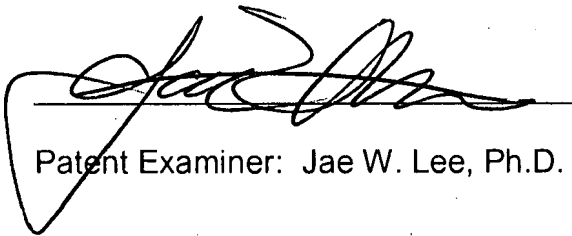
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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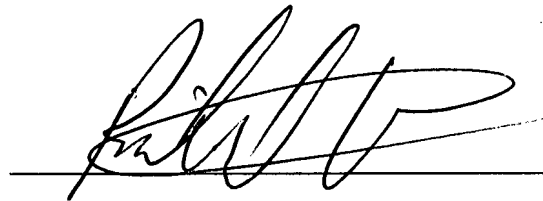
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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Patent Examiner: Jae W. Lee, Ph.D.



**RICHARD HUTSON, PH.D.**  
**PRIMARY EXAMINER**